With a non sterile standard kit

Constraints
- Complex traceability
- Contracted out sterilization
- Suppliers’ deadline

High costs
- $ Stocks
- $ Control
- $ Cleaning
- $ Decontamination
- $ Sterilization

Bulky storage

Complex process
1. Delivery
2. Storage
3. Unpacking
4. Control
5. Decontamination
6. Cleaning
7. Drying
8. Control
9. Packaging of the kit
10. Sterilization
11. Surgery
12. Decontamination
13. Cleaning
14. Drying
15. Control
16. Traceability
17. Restocking
18. Packaging of the kit
19. Sterilization
20. Storage

Prevents an effective solution & a quick response

URGENT SURGICAL CASES COMPROMISED

INCREASED RISKS
NON OPTIMAL surgery

INCOMPLETE kit

Defective sterilization

Incomplete kit

Damaged instrumentation
Safety

Cost efficiency
- Controlled stocks
- Simplified control
- 0 Cleaning
- 0 Decontamination
- 0 Sterilization

Optimized storage

Sundry expenses

Efficiency
- 1 Delivery
- 2 Storage
- 3 Surgery

Available when needed
- A problem solution & a quick response

Ready when you are!

Ready-to-use for surgery

With the kit

TRACEABILITY 100%

Sterile single use kit

Always new

Risk of contamination

Optimized handling of urgent surgical cases

Lapidus
**Available when needed:**
The Initial F™ Lapidus kit comes pre-sterilized and ready to use. The combination of sterile implants and single use instrumentation in a single packaging makes Initial F™ Lapidus ideal for use in urgent surgical cases.

**Costs:**
Initial F™ Lapidus is a cost-effective solution. The additional costs including cleaning, de-contamination, sterilization of kits are cancelled.

**Safety:**
The Initial F™ Lapidus kit is fully traceable and has a shelf life of 5 years. Its instrumentation and implants are “always new” and have never been opened or used before.

**Storage:**
Initial F™ Lapidus kit can be easily stored in the operating room because of its small size.

**Buying procedure:**
Initial F™ Lapidus facilitates buying procedures: restocking and orders are simplified, stock management is optimized.

**Contamination:**
The combination of sterile implants and sterile single-use instrumentation minimizes contamination risks.
**Initial F™ - Lapidus kit**

**Kit content**

Example: Kit LV1D - CQ4.0

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**Indications**

The implants of the Initial F™-Lapidus range are intended for arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults.

**Contraindications**

- Serious vascular deterioration, bone devitalization.
- Pregnancy.
- Acute or chronic local or systemic infections.
- Lack of musculo-cutaneous cover, severe vascular deficiency affecting the concerned area.
- Insufficient bone quality preventing a good fixation of the implants into the bone.
- Muscular deficit, neurological deficiency or behavioral disorders, which could submit the implant to abnormal mechanical strains.
- Allergy to one of the materials used or sensitivity to foreign bodies.
- Serious problems of non-compliance, mental or neurological disorders, failure to follow post-operative care recommendations.
- Unstable physical and/or mental condition.
Initial F™ - Lapidus Kit
Technical features

Plate for the plantar Lapidus arthrodesis

Examples of applications: osteoarthritis, functional deformities.

Compression screw
The compression screw is inserted through the joint providing stability to the assembly. The Ø4.0 mm cannulated headed screws (H1.4QT4.0Lxx-ST) are available separately on request in sterile version. The available range is from 26 mm to 48 mm with an incremental of 2 mm.

Plantar positioning of the plate
The positioning minimizes conflicts with the extensor hallucis longus and tibialis anterior tendons. Offers stable assembly and generates dynamic compression congruence between the plate and the bone.

Anatomical plate
The design of the implant is the result of a proprietary state-of-the-art mapping technology to establish maximum congruence between the plate and the bone.

Bending properties
The plate is made of Grade 2 Titanium, for an easier adaptation to the first tarsometatarsal (TMT1) joint anatomies when using the guide gauge.
Initial F™ - Lapidus kit
Instrumentation - Technical features

› 2-in-1 instrument: screwdriver and countersink
› T8 quick coupling screwdriver

The 2-in-1 instrument and the T8 quick coupling screwdriver can be used with the handle and the power tool. In the latter case, it is recommended to finalize the screwing by hand.

To release the 2-in-1 instrument or the T8 quick coupling screwdriver from the handle, press the button (a).

› Handle for guide gauge

Before performing the drilling into the oblong hole, snap the handle for guide gauge on the Ø2.7 mm threaded guide gauge.

› Template

The Initial F™ - Lapidus template is available separately and allows to quickly and simply determine the appropriate kit prior its opening. The template is bendable to fit the anatomy and select the desired plate size.
1. Select the correct kit according to the template.

2. Insert the Ø1.3 mm pin transversally from the 1st metatarsal to the first cuneiform. Connect the handle to the 2-in-1 instrument and slide it along the Ø1.3 mm pin and widen the surface of insertion using the countersink part of the 2-in-1 instrument. Then, slide the length gauge along the Ø1.3 mm pin to determine the length of the screw using the marking on the Ø1.3 mm pin.

3. Drill to prepare the screw insertion. The drilling depth can be checked using the marking on the drill bit. Select the appropriate screw length and insert the screw (H1.4QT4.0Lxx) along the Ø1.3 mm pin using the screwdriver part of the 2-in-1 instrument until the desired reduction and compression are achieved. Then remove the pin. NB: The Ø1.3 mm pin can be inserted deeper in order to prevent its removal during drilling.

4. Position the plate plantarly over the TMT1 joint and stabilize it temporarily by inserting a Ø1.2 mm pin. Snap the handle for guide gauge and perform the drilling using the assembly into the distal oblong hole. Determine the screw length using the length gauge (a).

5. Connect the handle to the screwdriver and insert a Ø3.5 mm pink anodized non-locking screw using the screwdriver. Repeat the same procedure for the proximal oblong hole.

6. Lock the Ø2.7 mm threaded guide gauge into the most distal hole and perform the drilling. Option 1: Determine the screw length using the drill bit and guide gauge. Option 2: Determine the screw length using the length gauge. Insert a Ø3.5 mm blue anodized locking screw using the screwdriver.

Final result

Finalize the assembly by inserting the Ø3.5 mm blue anodized locking screw into the proximal hole following the same procedure.
The Ø4.0 mm cannulated headed screws (H1.4QT4.0Lxx-ST) are available separately on request in sterile version. The available range is from 26 mm to 48 mm with an increment of 2 mm.

**INITIAL F™ - LAPIDUS KITS**

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>KIT-LV0D-CQ4.0</td>
<td>Lapidus Arthrodesis kit - Plantar plate - Right - Size 0 - for Ø4.0 mm headed cannulated screws</td>
</tr>
<tr>
<td>KIT-LV0G-CQ4.0</td>
<td>Lapidus Arthrodesis kit - Plantar plate - Left - Size 0 - for Ø4.0 mm headed cannulated screws</td>
</tr>
<tr>
<td>KIT-LV1D-CQ4.0</td>
<td>Lapidus Arthrodesis kit - Plantar plate - Right - Size 1 - for Ø4.0 mm headed cannulated screws</td>
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<td>Lapidus Arthrodesis kit - Plantar plate - Left - Size 1 - for Ø4.0 mm headed cannulated screws</td>
</tr>
<tr>
<td>KIT-LV2D-CQ4.0</td>
<td>Lapidus Arthrodesis kit - Plantar plate - Right - Size 2 - for Ø4.0 mm headed cannulated screws</td>
</tr>
<tr>
<td>KIT-LV2G-CQ4.0</td>
<td>Lapidus Arthrodesis kit - Plantar plate - Left - Size 2 - for Ø4.0 mm headed cannulated screws</td>
</tr>
</tbody>
</table>

**INITIAL F™ - LAPIDUS KITS - IMPLANTS CONTENT**

<table>
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</tr>
</tbody>
</table>

**INITIAL F™ - LAPIDUS KITS - INSTRUMENTATION CONTENT**

**STERILE INSTRUMENTATION FOR PLANTAR LAPIDUS PLATE**

<table>
<thead>
<tr>
<th>Description</th>
<th>Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ø2.7 mm quick coupling drill bit - L 125 mm</td>
<td>1</td>
</tr>
<tr>
<td>Ø2.7 mm threaded guide gauge for Ø3.5 mm screws</td>
<td>1</td>
</tr>
<tr>
<td>Length gauge for Ø2.8 and 3.5 mm screws - L8-40 mm</td>
<td>1</td>
</tr>
<tr>
<td>T8 quick coupling screwdriver</td>
<td>1</td>
</tr>
<tr>
<td>Handle for guide gauge</td>
<td>1</td>
</tr>
<tr>
<td>5.8 mm single use handle</td>
<td>1</td>
</tr>
<tr>
<td>Pin Ø1.6 L100 mm</td>
<td>1</td>
</tr>
<tr>
<td>Pin Ø1.2 L70 mm</td>
<td>2</td>
</tr>
</tbody>
</table>

**STERILE INSTRUMENTATION FOR Ø4.0 MM CANNULATED SCREWS**

<table>
<thead>
<tr>
<th>Description</th>
<th>Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length gauge for pin Ø1.3 mm - 120 mm</td>
<td>1</td>
</tr>
<tr>
<td>2 in 1:2.5 mm hexagonal screwdriver - Ø6.0 mm countersink</td>
<td>1</td>
</tr>
<tr>
<td>Ø2.9 mm drill bit - cannula 1.4 mm - L 120 mm - AO Ø4.5 mm quick coupling</td>
<td>1</td>
</tr>
<tr>
<td>Pin Ø1.3 L140 mm</td>
<td>3</td>
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</tbody>
</table>

* The Ø4.0 mm cannulated headed screws (H1.4QT4.0Lxx-ST) are available separately on request in sterile version. The available range is from 26 mm to 48 mm with an increment of 2 mm.
Initial F™ - Lapidus kits

References

Additional implants
Sterile screws packaged in the Supplemental sterile screw caddy

<table>
<thead>
<tr>
<th>NON LOCKING SCREWS - Ø3.5 mm*</th>
<th>Qty</th>
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<tbody>
<tr>
<td>RLT3.5L10-ST Non locking screw - Ø3.5mm - L 10 mm - STERILE</td>
<td>1</td>
</tr>
<tr>
<td>RLT3.5L12-ST Non locking screw - Ø3.5mm - L 12 mm - STERILE</td>
<td>1</td>
</tr>
<tr>
<td>RLT3.5L14-ST Non locking screw - Ø3.5mm - L 14 mm - STERILE</td>
<td>1</td>
</tr>
<tr>
<td>RLT3.5L16-ST Non locking screw - Ø3.5mm - L 16 mm - STERILE</td>
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</tr>
<tr>
<td>RLT3.5L18-ST Non locking screw - Ø3.5mm - L 18 mm - STERILE</td>
<td>1</td>
</tr>
<tr>
<td>RLT3.5L20-ST Non locking screw - Ø3.5mm - L 20 mm - STERILE</td>
<td>1</td>
</tr>
<tr>
<td>RLT3.5L22-ST Non locking screw - Ø3.5mm - L 22 mm - STERILE</td>
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</tr>
<tr>
<td>RLT3.5L24-ST Non locking screw - Ø3.5mm - L 24 mm - STERILE</td>
<td>1</td>
</tr>
<tr>
<td>RLT3.5L26-ST Non locking screw - Ø3.5mm - L 26 mm - STERILE</td>
<td>1</td>
</tr>
<tr>
<td>RLT3.5L28-ST Non locking screw - Ø3.5mm - L 28 mm - STERILE</td>
<td>1</td>
</tr>
<tr>
<td>RLT3.5L30-ST Non locking screw - Ø3.5mm - L 30 mm - STERILE</td>
<td>1</td>
</tr>
<tr>
<td>RLT3.5L32-ST Non locking screw - Ø3.5mm - L 32 mm - STERILE</td>
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<tr>
<td>RLT3.5L34-ST Non locking screw - Ø3.5mm - L 34 mm - STERILE</td>
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<tr>
<td>RLT3.5L36-ST Non locking screw - Ø3.5mm - L 36 mm - STERILE</td>
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<tr>
<td>RLT3.5L38-ST Non locking screw - Ø3.5mm - L 38 mm - STERILE</td>
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</tr>
<tr>
<td>RLT3.5L40-ST Non locking screw - Ø3.5mm - L 40 mm - STERILE</td>
<td>1</td>
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</table>

* Pink anodized

<table>
<thead>
<tr>
<th>LOCKING SCREWS - Ø3.5 mm*</th>
<th>Qty</th>
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</thead>
<tbody>
<tr>
<td>SLT3.5L10-ST Locking screw - Ø3.5mm - L 10 mm - STERILE</td>
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</tr>
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</tr>
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<tr>
<td>SLT3.5L34-ST Locking screw - Ø3.5mm - L 34 mm - STERILE</td>
<td>1</td>
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</tbody>
</table>

* Blue anodized

Removal and rescue kits
Sterile instruments

<table>
<thead>
<tr>
<th>REMOVAL AND RESCUE KITS - STERILE PACKAGING</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>KIT-REMOVE-2 Removal kit for T8 hexalobe</td>
<td>- 1x T8 Prehensor Screwdriver</td>
</tr>
<tr>
<td>KIT-REMOVE-A Removal kit for hexagonal 2.5</td>
<td>- 1x 2in1 2.5 mm Prehensor Screwdriver &amp; Ø3.5 mm countersink</td>
</tr>
</tbody>
</table>
| KIT-RESCUE-6 Rescue kit for Initial F Lapidus | - 1x Ø2.7 mm threaded guide gauge for Ø3.5 mm screws 
- 1x Ø2.7 mm quick coupling drill bit - L 125 mm 
- 1x Handle for guide gauge 
- 1x Length gauge 
- 1x Pin Ø1.6 L100 mm 
- 2x Pin Ø1.2 L70 mm |

Template
Sterile template

| INITIAL F™ - Lapidus template | ANCO958 | FLTDVx and FLTGVx template |

*Pink anodized*
Ready when you are!
## Example of kit content

### Implants material:
- **Plates**: Grade 2 Titanium - ISO 5832-2 / ASTM F67.

### Degree of accuracy for devices with a measuring function:
- ± 0.8 mm

### Instruments for Lapidus plate

<table>
<thead>
<tr>
<th>Size</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 mm</td>
<td>1 x</td>
</tr>
<tr>
<td>26 mm</td>
<td>1 x</td>
</tr>
<tr>
<td>28 mm</td>
<td>1 x</td>
</tr>
<tr>
<td>14 mm</td>
<td>1 x</td>
</tr>
<tr>
<td>16 mm</td>
<td>1 x</td>
</tr>
</tbody>
</table>

- **Non locking screws**: Ø3.5 mm
- **Locking screws**: Ø3.5 mm

### Instruments for cannulated screws*

<table>
<thead>
<tr>
<th>Size</th>
<th>Quantity</th>
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</thead>
<tbody>
<tr>
<td>14 mm</td>
<td>1 x</td>
</tr>
<tr>
<td>16 mm</td>
<td>1 x</td>
</tr>
<tr>
<td>20 mm</td>
<td>1 x</td>
</tr>
<tr>
<td>26 mm</td>
<td>1 x</td>
</tr>
</tbody>
</table>

### Handle for both

- Size 42 mm
- Size 11 mm

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*Non locking screws are not suitable for use with cannulated screws.*

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**Kit Content:**

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  - www.newcliptgmbh.de

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  - solutions@newclipaustralia.com
  - www.newcliptech.com

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  - Fax: +81 (0)3 58 25 49 86
  - www.newcliptechnics.fr

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**Lapidus arthrodesis**

*Plantar - Narrow - Size 1*